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EXAMINER

GRANO, ERNESTO ARTURIO

ART UNIT

PAPER NUMBER

3728

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. Receipt is acknowledged of Applicant's amendment filed on 03/30/2009.
 - Claim 1 was amended
 - Claim 9 was canceled
 - Claims 1-6 and 8 are presented for examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, recites the limitation "a support" in line 5. This limitation is indefinite and inconsistent and should be --the support--.

Claim 2-6 and 8 depend on claim 1.

Claim Rejections - 35 USC § 103

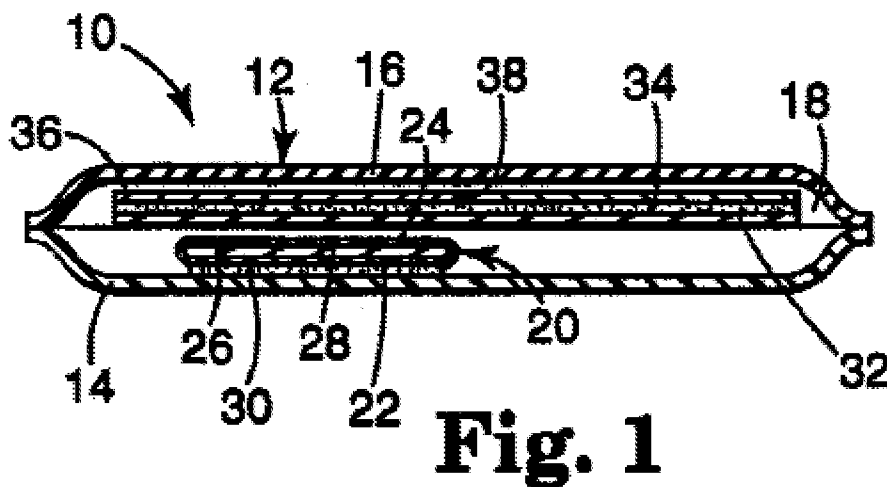
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said

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subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-6 and 8 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Wilking (US Patent 5,698,217) in view of Klokke et al (PG PUB US 2004/0086552), Kanios et al. (US Patent 6,905,016), Higo et al. (US 5,866,157), Asmussen et al. (US 6,267,982) and further view of Takayuki et al. (Japanese Patent 61-73547).



In re claim 1, with reference to figure 1, Wilking ('217) discloses a patch-containing packaging pouch (10) comprising: a packaging pouch (12); and a patch (38), housed within the packaging pouch (12), in which a pressure-sensitive adhesive layer (34) is formed on one side of a support, wherein the pressure-sensitive adhesive layer (34) is formed of a pressure-sensitive adhesive composition containing a pressure-sensitive adhesive and a dissolved drug.

However, Wilking ('217) fails to disclose a pressure-sensitive adhesive comprising at least one compound selected from the group consisting of a styrene-isoprene-styrene block copolymer, polyisobutylene and an acrylic polymer, and bisoprolol or pharmaceutically acceptable salt thereof, wherein the content of bisoprolol is 1 to 50% by mass in the pressure-sensitive adhesive composition, and relative humidity inside the packaging pouch at 25°C is maintained at 25% or less and wherein the packaging pouch has a layer formed from polyacrylonitrile on the innermost side.

Klokkers et al ('552) teaches a transdermal therapeutic system comprising a surface layer which is impervious with respect to an active ingredient, bisoprolol. (see page 3, paragraph 76)

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the patch (38) of Wilking ('217) with bisoprolol as its dissolved drug as taught by Klokkers et al ('552) in order to create a patch for treating people with a cardiovascular disease.

Kanios et al. ('016) teaches a product packaging system to prevent or control degradation reactions that can result from certain packaging materials and moisture contamination, which includes a pressure-sensitive adhesive made of an acrylic polymer. (see col. 7, lines 23-36)

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the pressure-sensitive adhesive of Wilking ('217) and Klokkers et al ('552) as applied above, to include an acrylic polymer

pressure-sensitive adhesive as taught by Kanios et al. ('016) in order to use an adhesive that will not have a reaction with certain drugs.

Higo et al. ('157) teaches organic acids and water-soluble salts which can be formulated in the amounts of 0.01 to 10% (w/w) based on the total amount of composition of the adhesive layer. (see column 3, lines 9-54)

Thus, It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the pressure-sensitive adhesive of Wilking ('217), Klokkers et al ('552), and Kanios et al. ('016) as applied above, with the drug content of 1 to 50% by mass as taught by Higo et al. ('157) in order to minimize skin irritation.

Asmussen et al. ('982) teaches a packaging pouch with a skin-adhering drug patch, which the air enclosed in the packaging pouch is adjusted to relative air humidity between 5% and below 0.5%. (see abstract and column 4, lines 2-13)

Thus, It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the packaging pouch of Wilking ('217), Klokkers et al ('552), Kanios et al. ('016), and Higo et al. ('157) as applied above, with relative air humidity between 5% and below 0.5% as taught by Asmussen et al. ('982) in order to keep the drug dissolved.

Takayuki et al. ('547) teaches an anti-inflammatory, analgesic drug packaging body formed by affixing a peel-off film configured from a polyacrylonitrile-based resin on the drug coated surface of a film-like anti-inflammatory, analgesic drug, and

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packaging and hermetically-sealing the same in a bag having an innermost layer of polyacrylonitrile-based resin which forms the innermost layer of the bag.

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the innermost layer of the packaging pouch (10) of Wilking ('217), Klokke et al ('552), Higo et al. ('157), and Asmussen et al. ('982) as applied above, to include a polyacrylonitrile-based resin as its inner most layer as taught by Takayuki et al. ('547) in order to keep moisture to a minimum within the package.

Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In re claim 2, Asmussen et al. ('982) discloses the relative humidity is maintained at 10% or less. (see column 4, lines 2-13)

In re claim 3, with reference to figure 1, Wilking ('217) discloses a desiccant (20) that is housed within the packaging pouch (12).

In re claim 4, with reference to figure 1, Wilking ('217) discloses a desiccant (20) is a desiccant (22 and 24) formed of a substance which physically adsorbs moisture. (see col. 3, lines 23-44)

In re claim 5, with reference to figure 1, Wilking ('217) discloses a desiccant (20) is a desiccant (22 and 24) formed of a porous substance. (see col. 4, lines 1-14)

In re claim 6, with reference to figure 1, Wilking ('217) discloses a desiccant (20) is a desiccant (22 and 24) formed of a porous substance formed of at least one type of

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material selected from the group comprising a metal oxide, zeolite and a clay mineral.
(see col. 4, lines 1-54)

In re claim 8, with reference to figure 1, Wilking ('217) discloses the packaging pouch (10) has a blocking layer (14) that blocks penetration of moisture. (see col. 6, lines 44-47)

Response to Arguments

6. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new grounds of rejection, which were previously made against canceled claim 9, which amended claim 1 is the same as in this amendment.

Conclusion

7. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNESTO A. GRANO whose telephone number is (571)270-3927. The examiner can normally be reached on 7:00am - 4:00pm Mon.-Thur..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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EAG

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